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09/406,473	09/27/1999	STEPHEN D. PACETTI	50623-00008	1646

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CAMERON KERRIGAN
SQUIRE, SANDERS & DEMPSEY LLP
ONE MARTINE PLAZA
SUITE 300
SAN FRANCISCO, CA 94111-3492

EXAMINER

THANH, LOAN H

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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/406,473
Filing Date: September 27, 1999
Appellant(s): PACETTI, STEPHEN D.

MAILED
OCT 05 2007
Group 3700

Mark Lupkowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/07/07 appealing from the Office action mailed 09/07/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5674192

Sahatjian et al.

10-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 139-154 are rejected under 35 U.S.C. 103(a) as obvious over Sahatjian et al. (U.S. Patent No. 5,674,192).

Sahatjian et al. disclose the invention substantially as claimed. Sahatjian et al. disclose a medical kit comprising a coated stent deployed by a balloon catheter wherein the stent is coated with a therapeutic substance. Further, it is disclosed that the sheath is made of polyurethane or TEFLON (fluorinated polymer). Sahatjian et al. teach the sheath is for protecting the drug/coating and for inhibiting premature release of the drug. The protective sheath is for preventing the release of the drug prior to reaching the desired location in the body. See col. 1-3, 8, 10-11, and 14. The Examiner is taking the position that it is inherent that the polyurethane has a glass transition temperature (T_g)

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that is above storage temperature. In the broadest interpretation the storage temperature has not been specified, thus the temperature can be any temperature.

Appellant is directed to MPEP 2112.01 reproduced below.

2112.01 Composition, Product, and Apparatus Claims [R-3] - 2100 Patentability

2112.01 Composition, Product, and Apparatus Claims [R-3]

I. PRODUCT AND APPARATUS CLAIMS - WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

See also *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated "such that the critical velocity of each successively larger panel will be less than the critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate." The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.); *Northam Warren Corp.*

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v. D. F. Newfield Co., 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

Further, it would be inherent for the Tg to be above storage temperature since the sheath would be a solid structure. If the Tg were below the storage temperature then the sheath would be unstable form during storage. It is inherent that the materials of the Sahatjian have the oxygen transmission rate as evidenced by Marotta (Packaging Forum) and further all materials have a water vapor transmission rate.

However, Sahatjian et al. does not disclose the non-polar soft segment to be hydrocarbons or silicones or fluorosilicons or mixtures thereof. It is common knowledge in the chemical art to modify the non-polar segments in order to provide properties such as flexibility and bendability which are desired in the medical arts. In absence of convincing objective evidence to the contrary, it would have been obvious to modify any medically acceptable material to the essential properties, which are desired.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Further it would have been obvious design choice lacking any criticality or unexpected results to modify the water vapor transmission rate as claimed. Properties of the material are easily modified in order to obtain through routine experimentation in determining optimum results. However these parameters are deemed matters of design

choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Further, applicant's specification has disclosed suitable combinations of barrier polymers and therapeutic substances but has also disclosed that other suitable combinations are possible. Applicant has also disclosed that in the broader aspects of the invention the sheath may not be in contact with the therapeutic agent and thus the therapeutic substance would not absorb or diffuse into the sheath material.

Applicant is suggested to show or provide criticality or unexpected results of the claimed properties of these materials.

(10) Response to Argument

With respect to Issue I of Appellant, Appellant is reminded that he is claiming a device claim having a "sheath material" with properties such as oxygen transmission rate at certain standard parameter and a water transmission rate at certain standard parameters. It is the Examiner's position that, Appellant has claimed (see claim 142-143, 145, 151) and specified in his specification this sheath material to be a polyurethane and since the Examiner 's prior art teaches the sheath to be the same material, it is inherent that the properties would also be the same as appellant's claims. Appellant is also reminded that there was an election of species which was mailed 04/02/04. Appellant responded by electing the species directed to a sheath and a specific material on 06/09/04.

Further, appellant's laundry list of materials appear to be substitutes of different materials which are interchangeable as described in appellant's specification. This is further evidence that appellant's choice of material is not critical, thus it would be further obvious to one of ordinary skill in the art to substitute any material that is known for the intended use or suitability of the material or properties which is/are desired in making of the sheath material.

With respect to Issue 2 of Appellant, it is inherent that if Appellant claims polyurethane, and the prior art discloses polyurethane that it would be meet the limitation and have the same properties such as that of the glass transition temperature (T_g). Further, all materials have T_g . Appellant has not specified what the T_g or the storage temperature, thus, in the broadest interpretation since the device of the prior art discloses the same material (polyurethane) that appellant is claiming it would be inherent that the prior art has the same properties as well lacking any further structurally distinguishing features.

With respect to appellant's argument that the Examiner is relying upon probabilities, the Examiner is not in agreement. The Examiner is interpreting the Appellant's broad claim language and applying the prior art of record as reasonably as possible. Appellant appears to be arguing more narrow than claimed. The Examiner is relying on the fact that appellant has claimed in a dependent claim the sheath material to be polyurethane. Sahatjian et al. discloses a sheath which is made of polyurethane thus it follows that if the dependent claim is polyurethane, thus the independent claim with the properties of the oxygen and water transmission rate is that

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of polyurethane and Sahatjian discloses polyurethane then Sahatjian et al. also has the oxygen and water transmission properties as claimed.

Further, with respect to appellant's reference to Sahatjian et al. disclosing Tecoflex™, the Examiner has not relied on this disclosure. The Examiner is relying on the disclosure of the sheath material being polyurethane or Teflon as disclosed by Sahatjian et al.

Further, the Examiner is not in agreement with Appellant that only applicants have recognized the suitability of polyurethane having a glass transition temperature above a storage temperature of a sheath material. It is well known in the polymer/material art that polyurethane materials are well known and that polyurethanes and all materials have properties such as Tg and that storage temperatures range from a variety of temperatures such as cold, warm and hot. Storage temperatures are temperatures which are desired in transporting or intermediate temperature or final disposition of the product. This storage temperature which appellant continues to argue is not even claimed within a specific range.

The Examiner made the 103 rejection not as an "obvious to try" rejection as appellant asserts. The Examiner is relying on the motivation that it is well known in the manufacturing arts that materials are well known to be varied to provide that device with properties which are desired by the user. It would be obvious to modify/substitute materials to provide more flexibility, bendability, etc. It is well known to the general

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artisan that known materials are chosen on the basis of their suitability , intended use, or desired properties.

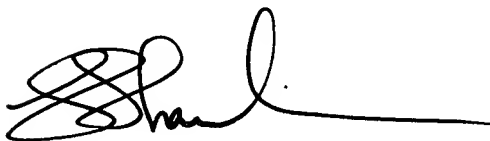
With respect to Issue 3, The Examiner is not persuaded by appellants arguments. The Examiner is reminding appellant that appellant has chosen in an earlier election the species of the sheath material. The Examiner is considering the limitation of the main group element oxide to not be positively claimed. The sheath material has a contacting surface which is considered by the Examiner to be the inner/internal surface of the sheath. The Examiner is considering the coating to be on the balloon which is not being positively recited. Thus, it is the Examiner's position that the sheath has a contacting surface which is capable of contacting a balloon which could have a main-group-element oxide.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', with a long horizontal line extending to the right.

LoAn H. Thanh

Conferees:

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NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Nick Lucchesi

Marc Jimenez 